

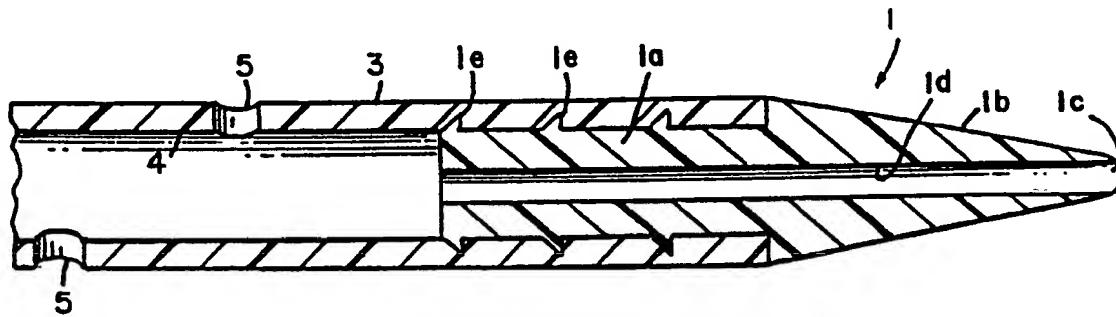


B2D

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 5 : A61M 5/32	A1	(11) International Publication Number: WO 91/07200 (43) International Publication Date: 30 May 1991 (30.05.91)
(21) International Application Number: PCT/US90/06524 (22) International Filing Date: 8 November 1990 (08.11.90)		(74) Agents: MEEGAN, Owen, J. et al.; 24 North Street, Salem, MA 01970 (US).
(30) Priority data: 437,048 13 November 1989 (13.11.89) US		(81) Designated States: AT (European patent), BE (European patent), CA, CH (European patent), DE (European patent), DK, DK (European patent), ES (European patent), FR (European patent), GB (European patent), GR (European patent), IT (European patent), JP, LU (European patent), NL (European patent), SE, SE (European patent).
(71) Applicant: BOSTON SCIENTIFIC CORPORATION [US/US]; 480 Pleasant Street, Watertown, MA 02172 (US). (72) Inventors: CHEVALIER, Raymond, P., Jr. ; 3793 Gilham Drive, Bloomington, IN 47403 (US). LACMAN, Joseph, J. ; 6571 N. Showers Road, Bloomington, IN 47401 (US). HUDSON, John, A. ; 141 Wellman Avenue, North Chelmsford, MA 01863 (US).		Published <i>With international search report.</i>

(54) Title: CATHETER WITH DISSOLVABLE TIP



(57) Abstract

The catheter of the present invention is adapted to be introduced into an internal organ in a body either percutaneously or through a body orifice for drainage of the organ where it can contact bodily fluids. The catheter includes a flexible tubular member (3) that has an inner lumen (4) and a rigid solid tip (1) disposed at the end of the inner lumen (4). The tip (1) is formed of a material that is slippery when wet, soluble in the bodily fluids and capable of absorbing radiographic fluids that are injected into inner lumen (4) for identification of the location by X-rays. A narrow passageway (1b) is disposed in the tip (1) and extends from the inner lumen (4) to the distal end (1c) of the tip (1). The passageway (1b) is adapted to receive a guide wire for insertion of the catheter into an internal organ.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	ES	Spain	MG	Madagascar
AU	Australia	FI	Finland	ML	Mali
BB	Barbados	FR	France	MR	Mauritania
BE	Belgium	GA	Gabon	MW	Malawi
BF	Burkina Faso	GB	United Kingdom	NL	Netherlands
BC	Bulgaria	GR	Greece	NO	Norway
BJ	Benin	HU	Hungary	PL	Poland
BR	Brazil	IT	Italy	RO	Romania
CA	Canada	JP	Japan	SD	Sudan
CF	Central African Republic	KP	Democratic People's Republic of Korea	SE	Sweden
CC	Congo	KR	Republic of Korea	SN	Senegal
CH	Switzerland	LJ	Liechtenstein	SU	Soviet Union
CI	Côte d'Ivoire	LK	Sri Lanka	TD	Chad
CM	Cameroon	LU	Luxembourg	TG	Togo
DE	Germany	MC	Monaco	US	United States of America
DK	Denmark				

CATHETER WITH DISSOLVABLE TIP

Background of the Invention

The present invention relates to a catheter that is to be placed into a body and may be guided into position on a guide wire into an organ for its drainage. Especially, the present invention relates to a catheter with an internal guiding passageway in a dissolvable tip so that when the catheter is in place in the organ, the tip will dissolve and allow drainage through the main lumen. In particular, the invention relates to a catheter with a tip that is slippery when wet, dissolvable in bodily fluids and has a composition which can absorb radiographic contrast liquids that are passed into it.

15

Description of the prior art

Many catheters are disclosed for insertion into organs of the body. To place the catheter in the correct location, the surgeon incises the body and inserts a guide wire (housed in a cannula) into the organ that is to be catheterized for drainage. The guide wire is temporarily anchored in the organ, the cannula is withdrawn, and the catheter is then advanced over the guide wire until it reaches the desired location in the organ. The guide wire is then withdrawn. The catheters of the prior art frequently have a blunt end and narrow opening formed therein. The opening is only slightly larger than the guide wire itself. Ports on the sidewalls of the catheter are relied on primarily for the drainage. The main lumen of the catheter itself, however, is not available for direct drainage because the body of the catheter is substantially sealed at the end since it only has an opening of a size that will receive the guide wire. Moreover, ultimate disposition of the catheter can be

misjudged by the surgeon because of placement of the blunt ends of some of the catheters are not readily detectable through X-rays.

Catheter with soluble tips are known to the art. For example, the United States patent to Taylor, 3,736,939, discloses a balloon inflated retention type catheter that has an imperforate, water soluble catheter tip which fits around the open end of the catheter tube. The United States patent to Bried, 2,691,373, discloses a colon flushing nozzle with a dissolvable tip. In Bried, a dissolvable hollow shell tip is disclosed which has a central opening that is of substantially the same width as the nozzle in which it fits. The United States patent to McShirley, 2,603,217, discloses a dissolvable tip that has a sleeve which fits over the end of the catheter for introducing fluids into a patient's body. A catheter having a dissolvable tip with a balloon located near the tip and an auxiliary drainage opening on the side of the catheter tube is disclosed by Taylor, 3,736,939.

20

Summary of the Invention

According to the present invention, the solid tip of the catheter is formed of a polymeric material that is slippery when wet and has a narrow central lumen so that the catheter may be easily advanced on the guide wire into the body, either percutaneously or through a body orifice, into the organ to be drained. Once there, the catheter tip will dissolve in the bodily fluids and eventually the entire lumen of the catheter will be available for drainage from the opening that is left when the tip dissolves. In many of the devices of the prior art, only ports that are disposed on the sidewalls of the tubular catheter were available for drainage. More efficient drainage is now available because the entire lumen is open to receive the bodily fluids that can be drained after the tip dissolves. Additionally, we have discov-

ered that through the use of certain polymeric materials that are slippery when wet and dissolvable in bodily fluids, these materials can absorb radiographic contrast liquids to become opaque to X-rays. Because of such absorption, the surgeon can easily inject a radiographic contrast liquid into the tubular member and thence into the tip to identify the precise location of the tip during a procedure.

Preferably, the solid tip is formed of a water soluble polymer such as polyvinyl alcohol although alternatives are available such as polyethylene oxide, polyethylene glycol, polyacrylamides, polyvinyl pyrrolidone, polyacrylic acid and the like. Such materials can be readily molded into a shape such as described herein.

The catheter includes a flexible tubular member having an inner lumen into which a portion of the tip fits. The tip is a solid unitary body. It has an external portion that is shaped in a generally conical configuration and an internal portion that has a generally cylindrical configuration, the cylindrical portion being disposed at the base of the cone. The internal portion is arranged to be disposed and rigidly held in the lumen. A narrow passageway is disposed axially through the tip and it extends from the mouth of the tip at the inner lumen of the tubular member to the distal end. The diameter of the passageway is substantially uniform from the mouth to the distal end. It is adapted to receive a guide wire for the insertion of the catheter into the internal organ and because of the fairly uniform diameter, the catheter will not tangle on the guide wire before it is seated in the organ.

Brief Description of the Drawings

Figure 1 is a side elevational view of a catheter and tip according to the present invention;

5 Figure 2 is an enlarged cross-sectional view taken along the line 2-2 of Figure 1 showing the catheter and tip with the tip disposed in the catheter.

Description of the Preferred Embodiments

10 Referring now to Figure 1, a catheter is shown which includes a flexible tubular member 3 formed of any of the polymeric materials conventionally used for catheters. The tubular member is biocompatible and inert to bodily fluids and optimally approaches a softness of body tissue so as to avoid irritation of tissues when the catheter is 15 in place. Materials having such characteristics include urethane, silicone and materials sold under the tradename "C-Flex" (sold by Concept, Inc., of Clearwater FL) and PERCUFLEX (provided by Medi-Tech, Inc., of Watertown, MA).

20 The catheter preferably has an outer diameter of about 27 to 53 mm. and the inner lumen has a diameter of about 1.6 to 4.0 mm. It is flexible so as to be movable within the body in which it is inserted. Auxiliary drainage ports 5 having diameters of about 0.5 to 6 mm. 25 are disposed in the wall of the catheter and communicate with the inner lumen. The auxiliary drainage ports 5 can be placed anywhere along the length of the catheter, as desired for effective drainage, as is well known in the art. In the embodiment that is shown, a suture 7 is 30 attached to the catheter to facilitate its removal when the need requires. A portion of the tip 1 is disposed inside the lumen of the catheter 3.

35 Referring now to Figure 2, the catheter tip 1 is shown disposed within the inner lumen 4 of the catheter 3. The tip 1 is formed of a unitary, stiff solid body of molded polymeric material and includes the inner portion

5 1a and an outer portion 1b. Outer portion 1b is formed
in a generally conical shape with a rounded distal end
1c. As shown, the tip 1 has a series of annular rings 1e
which extend outwardly from an inner portion 1a of the
tip 1 so as to anchor the tip firmly within the inner
lumen 4 of the catheter 3. While the tip 1 can be
anchored into the lumen 4 of the catheter 3 by the rings
as shown, heating and melting the tip and/or adhesives
can also be used to accomplish the fastening. Inner por-
10 tion 1a has a diameter substantially the same as the
inner diameter of the inner lumen 4 and is about 1.6 to
4.0 mm. The base of the outer portion 1b has a diameter
about 2.7 to 5.3 mm. and is substantially the same as the
diameter of the tubular member 3. The tip is preferably
15 formed of a polymeric material that has a hardness of
about 30 Shore D - about 40 Rockwell M. The tensile
strength is preferably between about 2,500 and 5,000 psi,
an elongation between about 25 and 500%.

20 A narrow axial passageway 1b having an internal
diameter of 0.45 to 1.27 mm. is disposed in the tip and
communicates between the lumen 4 and the distal end 1c.
The internal diameter of the passageway 1b is just
slightly greater than the diameter of the guide wire
which will be threaded through it. The diameter is
25 fairly uniform, although it can be slightly truncated to
easily receive the wire.

30 After the catheter is placed into organ to be
drained, the tip will dissolve at a predetermined rate
and the entire inner lumen 4 of the catheter 3 will be
available for drainage. Suitable materials for the tip 1
are those water soluble polymers set out previously.
Preferably the water solubility is about 45 seconds on a
1.5 mil thick sample in 25°C, water under slight agita-
35 tion. The slipperiness, based upon the coefficient of
friction is between about 0.02 and 0.3, preferably about
0.08.

These polymers may be used alone or in combination with water soluble non-toxic plasticizers, such as the various well known glycols or glycerols, to obtain the desired combination of rigidity and disintegration time.

5 The polymers chosen preferably will disintegrate and dissolve substantially completely when immersed in aqueous fluid over a predetermined number of hours or days, the adjustment of which is well known in the art.

10 Through the use of a catheter of the present invention, not only can fluids be removed but also substantial amounts of cellular debris and disconnected fragmented tissue which has become dislodged can be removed. In the catheters that do not open to the full lumen, such materials do not easily pass through the openings 5 due to 15 their small size. Such particles frequently tended to collect in or around the openings and impede the desired the drainage.

20 Quite surprisingly we have found that the polymeric materials that dissolve in bodily fluids can absorb radiographic contrast liquids that are injected into the catheter and ultimately into the passageway 1d. Since the tip 1 will absorb the radiographic contrast liquids, the tip itself will be rendered radio-opaque until total 25 dissolution is complete, thus rendering its location amenable to identification by X-ray.

30 Additionally we have found that the materials of the tip can be color coded in an array of colors by mixing non-toxic coloring agents into the polymeric blend to enable the user to easily identify catheters of different diameters or dissolution rates.

To make the catheter tip, we have found that the following procedure provides a device that is adequate for its use with the catheter tube.

35 The tip may be formed and is most preferred to be formed by conventional thermoplastic processing methods. One such method that is employed is injection molding.

5 This process can be described as one that produces three dimensional parts through a discontinuous start and stop process. For example, polyvinyl alcohol may be used containing up to approximately 60% by weight propylene glycol. It is dried for a period of approximately four hours at 80°C. The material may then be processed in an injection molding machine at a melt temperature between 10 140 and 220°C, preferably 170°C. The part is then removed from the mold after it has cooled and then secured to the tubing.

15 It is apparent that modifications and changes can be made within the spirit and scope of the present invention. It is our intention, however, only to be limited by the scope of the appended claims.

15 As our invention, we claim.

1 1. A catheter to be introduced into an internal
2 organ in a body either percutaneously or through a body
3 orifice where it can contact bodily fluids, said catheter
4 comprising:

5 a flexible tubular member having an inner lumen;
6 a rigid solid tip having an inner face and a distal
7 end, said tip being disposed at the opening of said tubu-
8 lar member, said tip being formed of a polymeric material
9 that is slippery when wet, soluble in said bodily fluids
10 and able to absorb radiographic media injected into said
11 tubular member whereby to render said tip radio-opaque;
12 a narrow passageway disposed in said tip, said pas-
13 sageway extending from said inner face to the distal end
14 of said tip, said passageway being adapted to receive a
15 guide wire for the insertion of said catheter into an
16 internal organ.

17

18 2. The catheter according to claim 1 wherein a por-
19 tion of said tip is disposed inside of said inner lumen.
20

21 3. The catheter according to claim 1 wherein said
22 tip is a unitary body and said passageway extends through
23 said tip on its long axis, said tip having an external
24 portion shaped in a generally conical configuration and
25 an internal portion having a generally cylindrical con-
26 figuration, said internal portion being arranged to be
27 disposed in said lumen, said internal portion extending
28 coaxially from the base of said external portion and
29 being disposed within said tubular member.
30

31 4. The catheter according to claim 3 wherein the
32 outer diameter of said internal portion has a diameter
33 substantially the same as the internal diameter of said
34 inner lumen.

1 5. The catheter according to claim 4 wherein the
2 internal diameter of said inner lumen is between about
3 1.6 and 4.0 mm. and the outer diameter of said internal
4 portion is between about 2.7 and 5.3 mm.

5
6 6. The catheter according to claim 3 wherein the
7 outer diameter of the tubular member is substantially the
8 same as the diameter of the base of the cone of said tip.

9
10 7. The catheter according to claim 1 further includ-
11 ing fastening means connecting said tip to said inner
12 lumen,

13
14 8. The catheter according to claim 3 wherein said
15 fastening means are a series of annular rings disposed on
16 said inner portion of said tip.

17
18 9. The catheter according to claim 3 wherein said
19 fastening means includes adhesives.

20
21 10. The catheter according to claim 1 the tip is
22 formed of a water soluble material selected from the
23 group consisting of polyvinyl alcohol, polyethylene
24 oxide, polyethylene glycol, polyacrylamides, polyvinyl
25 pyrrolidone, polyacrylic acid and the like.

26
27 11. The catheter according to claim 3 wherein the
28 material is polyvinyl alcohol.

29
30 12. The catheter according to claim 1 wherein the
31 diameter of said passageway is significantly less than
32 the diameter of said inner lumen.

33
34 13. The catheter according to claim 11 wherein the
35 diameter of said passageway is between about 0.45 and
36 1.27 mm.

1 14. The catheter according to claim 12 wherein the
2 passageway has a fairly uniform diameter from the inner
3 face to the distal tip.

4
5 15. The catheter according to claim 1 wherein a plu-
6 rality of openings are formed on the sidewalls of said
7 tubular member.

8
9 16. A catheter to be introduced into an internal
10 organ in a body either percutaneously or through a body
11 orifice where it can contact bodily fluids, said catheter
12 comprising:

13 a flexible tubular member having an inner lumen;
14 a rigid solid tip having an inner face and a distal
15 end, said tip being disposed at the opening of said tubu-
16 lar member, said tip being formed of a polymeric material
17 that is slippery when wet, soluble in said bodily fluids
18 and able to absorb radiographic media injected into said
19 tubular member whereby to render said tip radio-opaque,
20 said tip being a unitary body, said tip having an exter-
21 nal portion shaped in a generally conical configuration
22 and an internal portion having a generally cylindrical
23 configuration, said internal portion being arranged to be
24 disposed in said lumen, said internal portion extending
25 coaxially from the base of said external portion and
26 being disposed within said tubular member;

27 a narrow passageway disposed in said tip, said pas-
28 sageway extending from said inner face to the distal end
29 of said tip, said passageway adaptable to receive a guide
30 wire for the insertion of said catheter into an internal
31 organ.

1 17. The catheter according to claim 16 wherein the
2 outer diameter of said internal portion has a diameter
3 substantially the same as the internal diameter of said
4 inner lumen.

5

6 18. The catheter according to claim 17 wherein the
7 internal diameter of said inner lumen is between about
8 1.6 and 4.0 mm. and the outer diameter of said internal
9 portion is between about 2.7 and 5.3 mm.

10

11 19. The catheter according to claim 17 wherein the
12 outer diameter of the tubular member is substantially the
13 same as the diameter of the base of the cone of said tip.

14

15 20. The catheter according to claim 16 further
16 including fastening means connecting said tip to said
17 inner lumen.

18

19 21. The catheter according to claim 20 wherein said
20 fastening means are a series of annular rings disposed on
21 said inner portion of said tip.

22

23 22. The catheter according to claim 16 the tip is
24 formed of a water soluble material selected from the
25 group consisting of polyvinyl alcohol, polyethylene
26 oxide, polyethylene glycol, polyacrylamides, polyvinyl
27 pyrrolidone, polyacrylic acid and the like.

28

29 23. The catheter according to claim 22 wherein the
30 material is polyvinyl alcohol.

31

32 24. The catheter according to claim 16 wherein the
33 diameter of said passageway is significantly less than
34 the diameter of said inner lumen.

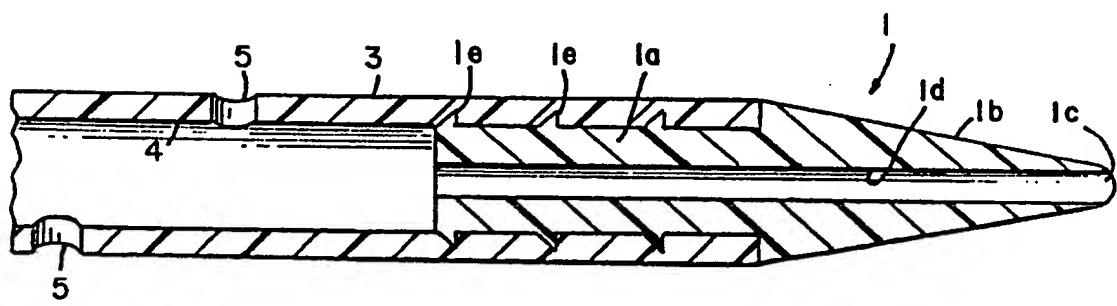
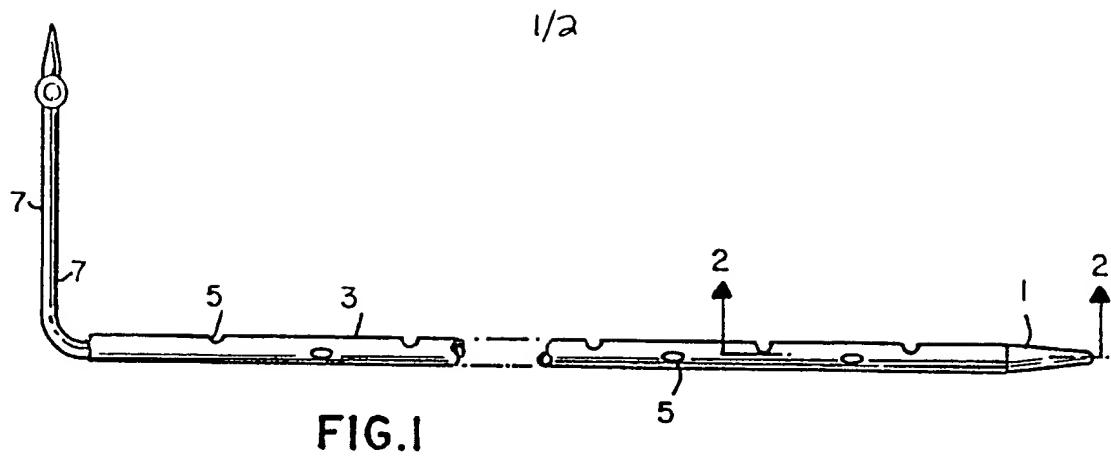
1 25. The catheter according to claim 24 wherein a
2 plurality of openings are formed on the sidewalls of said
3 tubular member.

4

5 26. The catheter according to claim 13 wherein a
6 plurality of openings are formed on the sidewalls of said
7 tubular member.

8

9 27. The catheter according to claim 15 wherein said
10 tip is color coded in a predetermined array of colors to
11 designate the diameter of the catheter and/or the disso-
12 lution rate.



2/2

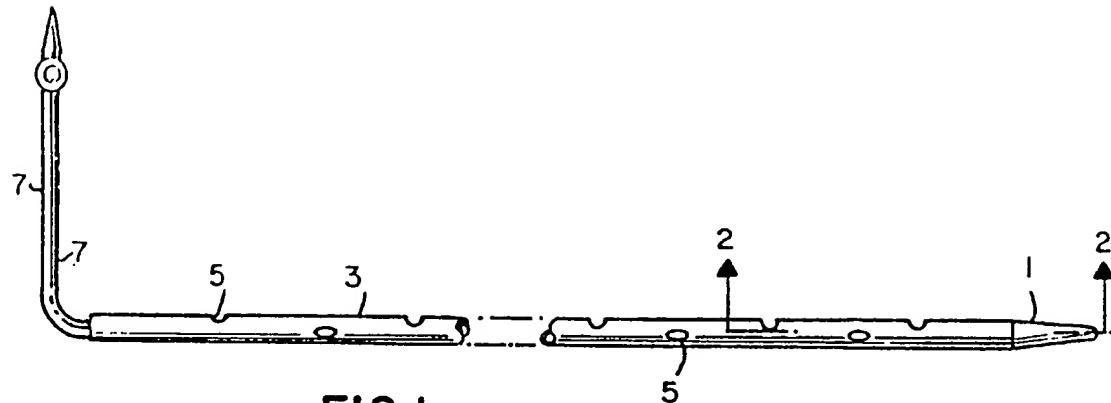


FIG.1

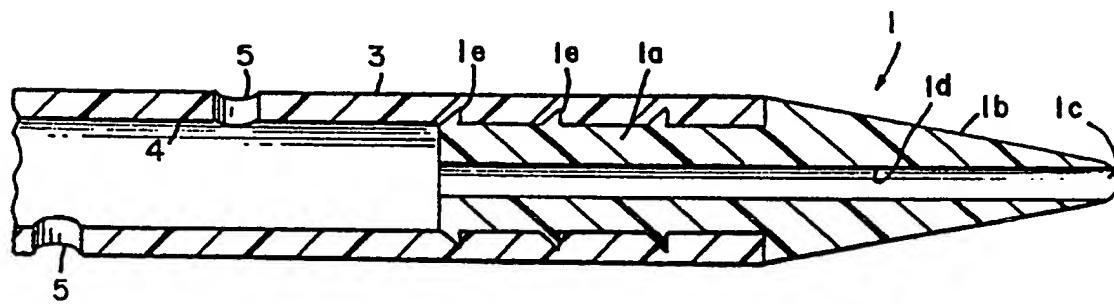


FIG.2

INTERNATIONAL SEARCH REPORT

International Application No. PCT/US90/06524

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) ²

According to International Patent Classification (IPC) or to both National Classification and IPC

US CL.: 604/265

IPC(5): A61M 5/32

II. FIELDS SEARCHED

Minimum Documentation Searched ⁴

Classification System	Classification Symbols
US	604/52-53, 171-172, 264-266, 270
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched ⁵	

III. DOCUMENTS CONSIDERED TO BE RELEVANT ¹⁴

Category ⁶	Citation of Document, ¹⁵ with Indication, where appropriate, of the relevant passages ¹¹	Relevant to Claim No. ¹⁸
Y	US, A, 4,698,056 (CIANNELLA) 06 October 1987 Refer to figure 2.	1-7, 9, 11-14, 16- 20, 24, 27
Y	US, A, 4,876,126 (TAKEMURA et al.) 24 October 1989 Refer to figure 2, examples 1 and 3 of columns 9 and column 4, lines 30-39.	1-7, 9, 11-14, 16- 20, 24, 27
A	US, A, 4,790,310 (GINSEBURG et al.) 13 December 1988 Refer to column 3.	1-27
Y	US, A, 4,827,940 (MAYER et al.) 09 May 1989 Refer to column 3, line 31.	10, 22, 23
Y	US, A, 3,780,740 (RHEA) 25 December 1973 Refer to abstract.	15, 25, 26

* Special categories of cited documents: ¹⁵

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search ¹

30 JANUARY 1991

Date of Mailing of this International Search Report ¹

04 MAR 1991

International Searching Authority ¹

ISA?US

Signature of Authorized Officer *NGOC-HO*
INTERNATIONAL DIVISION

Fn CORRINE MAGLIONE *Monette Nguyen*